Complete Summary

GUIDELINE TITLE

Etanercept and infliximab for the treatment of adults with psoriatic arthritis.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Etanercept and infliximab for the treatment of adults with psoriatic arthritis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jul. 33 p. (Technology appraisal guidance; no. 104).

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references drug(s) for which important revised regulatory and/or warning information has been released.

• May 1, 2008, Enbrel (etanercept): Amgen and Wyeth Pharmaceuticals informed healthcare professionals of changes to the BOXED WARNING section of the prescribing information for Enbrel regarding the risk of serious infections, including bacterial sepsis and tuberculosis, leading to hospitalization or death. The ADVERSE REACTIONS section of the label was updated to include information regarding global clinical studies and the rate of occurrence of tuberculosis in patients treated with Enbrel.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

SCOPE

DISEASE/CONDITION(S)

Psoriatic arthritis (PsA, psoriatic arthropathy)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness Management Treatment

CLINICAL SPECIALTY

Dermatology Family Practice Pharmacology Rheumatology

INTENDED USERS

Advanced Practice Nurses Nurses Pharmacists Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness, safety, tolerability, and cost effectiveness of etanercept and infliximab for the treatment of active and progressive psoriatic arthritis

TARGET POPULATION

Adults with active and progressive psoriatic arthritis who have inadequate response to standard treatment (including disease modifying antirheumatic drug [DMARD] therapy)

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Etanercept
- 2. Infliximab

MAJOR OUTCOMES CONSIDERED

Clinical effectiveness

- Measures of disease activity
 - The American College of Rheumatology (ACR) joint count
 - The Psoriatic Arthritis Response Criteria (PsARC)
 - The Psoriasis Area and Severity Index (PASI)
- Function and quality of life (Health Assessment Questionnaire [HAQ])
- Radiological assessment of disease progression
- Adverse events
- Cost-effectiveness of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Centre for Reviews and Dissemination/ Centre for Health Economics (CRD/CHE) Technology Assessment Group, University of York (see the "Availability of Companion Documents" field.)

Search Strategy

Searches were undertaken on the following databases to identify relevant clinical and cost-effectiveness research. Full details of the search strategies are reported in Appendix 10.1 of the Assessment Report (see "Availability of Companion Documents" field):

- Medline and In-Process Citations (OVID Online http://www.ovid.com/)
- Embase (OVID Online http://www.ovid.com/)
- National Research Register (NRR) (cd-rom)
- Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Library via the internet - http://www.update-software.com/clibng/cliblogon.htm)
- CenterWatch (internet http://www.centerwatch.com/index.html)
- Current Controlled Trials (internet http://controlled-trials.com/)
- ClinicalTrials.gov (internet http://clinicaltrials.gov/)
- National Health Service Economic Evaluation Database (NHS EED) (CRD administration database)
- Health Economic Evaluation Database (HEED) (cd-rom)
- EconLit (SilverPlatter on the web via ARC2 WebSPIRS http://arc.uk.ovid.com/)
- ISI Science and Technology Proceedings (Web of Knowledge http://wos.mimas.ac.uk/)
- Social Science Citation Index (Web of Science http://wos.mimas.ac.uk/)

Science Citation Index (Web of Science - http://wos.mimas.ac.uk/)

All databases were searched from their inception to the date of the search. No language or other restrictions were applied.

Searches were also undertaken on several Internet resources, which are documented in Appendix 10.1 of the Assessment Report (see "Availability of Companion Documents" field).

Searches took place over a period of time from April to July 2004.

Terminology

The terms for the search strategies were identified through discussion between an Information Officer and the research team, by scanning the background literature, and by browsing the Medline Medical Subject Headings (MeSH).

Management of References

As several databases were searched, some degree of duplication resulted. To manage this issue, the titles and abstracts of bibliographic records were downloaded and imported into Endnote bibliographic management software to remove duplicate records.

Handsearching

The bibliographies of all included studies and industry submissions made to NICE were reviewed to identify further relevant studies. Handsearching continued throughout the project.

Additional Searches

Additional searches (including citation searches on key papers) were completed as required. See Appendix 1 of the Assessment Report (see "Availability of Companion Documents" field) for full details.

Inclusion and Exclusion of Studies

Study Selection

Two reviewers selected the studies for the review. Discrepancies were resolved by consensus and a third reviewer was consulted when necessary. Each reviewer's decision and a final decision were recorded in the Endnote library.

All titles and abstracts identified by the search were screened and any references that were considered relevant by either reviewer were obtained.

No language restrictions were applied to study selection. Trials reported as full publications or unpublished full reports were included as abstracts only were to be

included if adequate information was provided. All of the data submitted by Wyeth and Schering-Plough were considered in the review.

Inclusion/Exclusion Criteria

Studies were included in the review according to the inclusion criteria described in the following paragraphs.

Efficacy of Interventions

The review addressed the following questions about the efficacy of etanercept and infliximab in the treatment of psoriatic arthritis:

- Is treatment effective at all?
- How effective is the treatment?
- Is the drug effective long-term?
- Is there evidence of effect on disease progression?
- Is there is evidence that treatment has a beneficial effect on the psoriasis component of the disease?
- Is there is evidence that treatment improves the functional status of patients?

Intervention

Etanercept administered by subcutaneous injection (SC) and infliximab administered by intravenous infusion were the interventions of interest. Comparisons with either placebo or any other active agent were eligible for inclusion. Trials that compared different regimens of the same disease modifying antirheumatic drug (DMARD) or compared a DMARD with or without a concomitant agent were not included in the review; all such trials identified are listed under excluded studies in Appendix 10.3 of the Assessment Report (see "Availability of Companion Documents" field).

Participants

Studies of adults with psoriatic arthritis were included.

Study Design

Randomised controlled trials were included in the evaluation of efficacy.

Outcomes

The outcomes of primary interest were those of disease activity (those derived from the American College of Rheumatology (ACR) joint count; the Psoriatic Arthritis Response Criteria (PsARC), and the Psoriasis Area and Severity Index (PASI) based measures), those of function and quality of life (Health Assessment Questionnaire (HAQ)) and those of radiological assessment of disease progression. Other outcomes measures of disease activity, function and quality of life and disease progression were considered as necessary given the available trials.

For details of the inclusion/exclusion criteria for studies of adverse events of interventions and disease modifying anti-rheumatoid drugs for treatment of psoriatic arthritis, see sections 3.2.2.2 and 3.2.2.3 in the Assessment Report (see "Availability of Companion Documents" field).

<u>Economic Evaluations – Systematic Review</u>

Studies were eligible for inclusion if they assessed both the costs and benefits (i.e., a full economic evaluation) of either etanercept or infliximab, and compared findings with an appropriate comparator treatment.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

Etanercept

Two randomised controlled trials (RCTs, n = 265) were included in the Assessment Report.

Infliximab

One RCT was included in the Assessment Report.

Cost Effectiveness

The search strategy for published economic evaluations yielded 117 potentially relevant studies. Of these, none fulfilled the inclusion criteria of being a full economic evaluation of etanercept or infliximab for the treatment of psoriatic arthritis.

Two cost-effectiveness models were received from manufacturers, one for etanercept (from Wyeth) and one for infliximab (from Schering Plough).

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Centre for Reviews and Dissemination/ Centre for Health Economics (CRD/CHE) Technology Assessment Group, University of York (see the "Availability of Companion Documents" field.)

For details of the data extraction and quality assessment strategies, see sections 3.2.3 and 3.2.4 in the Assessment Report (see "Availability of Companion Documents" field).

Data Analysis

Efficacy of Interventions

Full data extraction and quality assessment have been presented for each efficacy trial of etanercept and infliximab.

Results have been summarised in tables and the effect of trial quality on the efficacy findings is discussed. Relative risks (RRs) and mean differences were calculated for the primary outcomes with 95% confidence intervals (CIs); the primary outcome variables were American College of Rheumatology response criteria (ACR) 20, ACR 50, ACR 70, Psoriatic Arthritis Response Criteria (PsARC), Health Assessment Questionnaire (HAQ), and Psoriasis Area and Severity Index (PASI).

Clinical diversity of the trials regarding adult status, minimum PASI score, and concomitant medication was considered. Where the trials were not clinically diverse (heterogeneous) the data were pooled. Statistical heterogeneity was investigated using the Chi-Squared test; where it was statistically significant data were not pooled. Where pooling was appropriate, pooled RRs (95% CI) or weighted mean differences (WMD) (95% CI) were calculated using a fixed effect model. A fixed effect model was selected because a small number of trials were included in the meta-analysis, and a fixed effect model was therefore considered most appropriate due to the smaller estimation of between-study variance.

In order to generate appropriately pooled estimates of clinical parameters for the cost-effectiveness modelling an evidence synthesis was conducted. The exact specification of the synthesis depended on the nature of the trial evidence and the details of the cost-effectiveness models; unless head-to-head trials comparing etanercept and infliximab are identified, the synthesis would be likely to take the form of a mixed treatment comparison. The detailed methods of the evidence synthesis are described in Section 4.2.3 of the Assessment Report (see the "Availability of Companion Documents" field).

Adverse Effects of Interventions

Results have been summarised in tables and the findings are discussed in a narrative synthesis. Adverse events data have been grouped by duration of follow-up.

DMARDs for Treatment of Psoriatic Arthritis

Data extraction has been presented for each comparator trial. Results have been summarised in tables and the findings are discussed. Relative risks (RRs) and mean differences were calculated for the primary outcomes with 95% confidence intervals (CIs); the primary outcome variables were ACR 20, ACR 50, ACR 70, PsARC, Tender Joint Score (mean change from baseline), Erythrocyte sedimentation rate (ESR) (mean change from baseline mm/h), Pain (mean change from baseline, visual analog scale [VAS]), Swollen Joint Score (mean change from baseline), Patient Global Assessment (mean change from baseline), HAQ (mean change from baseline) and PASI (mean change from baseline).

The findings were not pooled statistically due to the clinical diversity of the trials and the small numbers of studies investigating the same treatment comparison.

Economic Evaluations -Systematic Review

Any published economic evaluations were to be described but no formal synthesis was planned. This also applied to submitted analyses from manufacturers, although additional analyses using their electronic models was to have been considered. In the event no published economic evaluation on anti-TNF drugs for the treatment of psoriatic arthritis was identified.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost-effectiveness models were submitted by Wyeth and Schering Plough. Wyeth's model estimated the incremental cost per quality adjusted life years (QALY) gained for etanercept (compared to a composite comparator) to range from 28,189 pounds sterling for a 10-year time horizon to 66,580 pounds sterling for a 6-month time horizon. Schering Plough presented two models. The "Active Joint" model estimated an incremental cost per QALY gained for infliximab of 36,786 pounds sterling (5-year time horizon). The "Chronic Active Joint" model estimated an incremental cost-effectiveness ratio (ICER) of 33,877 pounds sterling (30-year time horizon).

Given some potential limitations of the manufacturers' models and their failure to compare the two biological therapies directly and with palliative care, a new model was developed (the York Model). Results were estimated over a range of time horizons and based on a number of alternative assumptions. Infliximab is

consistently dominated by etanercept because of its higher acquisition and administration costs without superior effectiveness. The incremental cost per QALY gained of etanercept compared with palliative care ranges from 14,806 pounds sterling (females, 40-year time horizon) to 49,299 pounds sterling (males, 1-year time horizon) if it is assumed that, when patients eventually fail on biological therapy, their disability (in terms of Health Assessment Questionnaire [HAQ] score) deteriorates by the same amount as it improved when they initially respond to treatment (rebound equal to gain). The ICERs of etanercept range from 25,403 pounds sterling (females, 40-year time horizon) to 49,408 pounds sterling (males, 1-year time horizon) if it is assumed that, when patients fail on therapy, their disability level returns to what it would have been had they never responded (rebound equal to natural history).

See section 4.2 in the original guideline document for a full discussion of cost effectiveness.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- 1. Etanercept, within its licensed indications, is recommended for the treatment of adults with severe active psoriatic arthritis only when the following criteria are met.
 - The person has peripheral arthritis with three or more tender joints and three or more swollen joints.
 - The psoriatic arthritis has not responded to adequate trials of at least two standard disease-modifying anti-rheumatic drugs (DMARDs), administered either individually or in combination.
- Etanercept treatment should be discontinued in patients whose psoriatic arthritis has not shown an adequate response when assessed using the Psoriatic Arthritis Response Criteria (PsARC) at 12 weeks. An adequate response is defined as:

- An improvement in at least two of the four PsARC criteria, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria
- 3. Infliximab, within its licensed indications, is recommended for the treatment of adults with severe active psoriatic arthritis if, under the circumstances outlined in section 1 (above), treatment with an anti-tumour necrosis factor (TNF) agent is considered appropriate and the person has been shown to be intolerant of, or have contraindications to, treatment with etanercept or has major difficulties with self administered injections.
- 4. Infliximab treatment should be discontinued in patients whose psoriatic arthritis has not responded adequately at 12 weeks. An adequate response is defined in section 2 (above).
- 5. It is recommended that the use of etanercept or infliximab for psoriatic arthritis should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of psoriatic arthritis. If a person has both psoriatic arthritis and psoriasis their treatment should be managed by collaboration between a rheumatologist and a dermatologist.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of etanercept and infliximab for the treatment of adults with psoriatic arthritis

POTENTIAL HARMS

Etanercept

The Summary of Product Characteristics states that research into the long-term safety of combinations of etanercept with methotrexate is ongoing, and that the long-term safety of etanercept in combination with other disease-modifying anti-rheumatic drugs (DMARDs) has not been established.

The most frequent adverse events reported during etanercept therapy include injection-site reactions, infections and allergic reactions. The Summary of Product Characteristics specifies a number of uncommon but serious adverse events that may be related to the immunomodulatory activity. There are no monitoring requirements.

Infliximab

The most common adverse events reported during infliximab therapy include acute-infusion-related reactions, infections, and delayed hypersensitivity reactions. The Summary of Product Characteristics specifies a number of uncommon but serious adverse events related to the immunomodulatory activity.

For full details of side effects and contraindications, see the Summary of Product Characteristics for each drug, available at http://emc.medicines.org.uk/

CONTRAINDICATIONS

CONTRAINDICATIONS

Infliximab

The Summary of Product Characteristics (SmPC) states that infliximab is contraindicated in people with moderate or severe heart failure, and before treatment is initiated, people must be screened for both active and inactive tuberculosis.

For full details of side effects and contraindications, see the Summary of Product Characteristics for each drug, available at http://emc.medicines.org.uk/

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Notes on the Generalisability of the Findings

The efficacy data used in the clinical evaluation, evidence synthesis and the economic models are very limited, being derived from a total of three trials and a total of 369 patients, with only 134 patients treated with etanercept and 52 treated with infliximab. Furthermore, these trial populations were not precisely representative of those for whom etanercept and infliximab are licenced: neither population was made up exclusively of patients who had failed to respond to at least two disease-modifying anti-rheumatic drugs (DMARDs). A number of other parameters within the economic models are also based on very limited evidence.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (<u>www.nice.org.uk/TA103</u> [see also the "Availability of Companion Documents" field]).
 - Costing report and costing template to estimate the savings and costs associated with implementation.
 - Audit criteria to monitor local practice (see appendix C of the original guideline document).

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Etanercept and infliximab for the treatment of adults with psoriatic arthritis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jul. 33 p. (Technology appraisal guidance; no. 104).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Jul

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Ms Julie Acred, Chief Executive Officer, Derby Hospitals; Dr Darren Ashcroft, Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences, University of Manchester; Professor David Barnett (Chair) Professor of Clinical Pharmacology, University of Leicester; Dr Peter Barry, Consultant in Paediatric Intensive Care and Honorary Senior Lecturer, Department of Child Health, Leicester Royal Infirmary; Mr Brian Buckley, Vice Chairman, InContact; Professor Mike Campbell, Statistician, Institute of General Practice & Primary Care, Sheffield; Dr Mark Chakravarty, Head of Government Affairs and NHS Policy, Procter and Gamble Pharmaceuticals (UK) Ltd, Egham, Surrey; Dr Peter I Clark, Consultant Medical Oncologist, Clatterbridge Centre for Oncology, Wirral, Merseyside; Ms Donna Covey, Chief Executive, Asthma UK; Dr Mike Davies Consultant Physician, University Department of Medicine & Metabolism, Manchester Royal Infirmary; Mr Richard Devereaux-Phillips, Public Affairs Manager, Medtronic Ltd; Professor Jack Dowie, Health Economist, London School of Hygiene; Professor Gary A Ford (Vice Chair) Professor of Pharmacology of Old Age/Consultant Physician, Newcastle upon Tyne Hospitals NHS Trust; Dr Fergus Gleeson, Consultant Radiologist, The Churchill Hospital, Oxford; Ms Sally Gooch, Former Director of Nursing, Mid-Essex Hospital Services NHS Trust, Chelmsford;

Professor Trisha Greenhalgh, Professor of Primary Health Care, University College London; Miss Linda Hands, Clinical Reader in Surgery, University of Oxford; Professor Peter Jones, Professor of Statistics & Dean Faculty of Natural Sciences, Keele University; Professor Robert Kerwin, Professor of Psychiatry and Clinical Pharmacology, Institute of Psychiatry, London; Ms Rachel Lewis, Nurse Advisor to the Department of Health; Professor Jonathan Michaels, Professor of Vascular Surgery, University of Sheffield; Dr Ruairidh Milne, Senior Lecturer in Public Health, National Coordinating Centre for Health Technology Assessment, University of Southampton; Dr Neil Milner, General Medical Practitioner, Sheffield; Dr Rubin Minhas, General Practitioner with a Special Interest in Coronary Heart Disease, Primary Care CHD Lead, Medway PCT & Swale PCT; Mr Miles Scott, Chief Executive, Harrogate Health Care NHS Trust; Professor Mark Sculpher, Professor of Health Economics, University of York; Dr Ken Stein, Senior Lecturer, Peninsula Technology Assessment Group (PenTAG), University of Exeter; Professor Andrew Stevens Professor of Public Health, University of Birmingham; Ms Jayne Wilson, Systematic Reviewer, WMHTAC, Department of Public Health and Epidemiology

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Etanercept and infliximab for the treatment of adults with psoriatic arthritis.
 Quick reference guide. London (UK): National Institute for Health and Clinical
 Excellence (NICE); 2006 Jul. 2 p. (Technology appraisal 104). Available in
 Portable Document Format (PDF) from the National Institute for Health and
 Clinical Excellence (NICE) Web site.
- Costing template and costing report. Etanercept and infliximab for the
 treatment of adults with psoriatic arthritis. London (UK): National Institute for
 Health and Clinical Excellence (NICE); 2006 Jul. Various p. (Technology
 appraisal 104). Available in Portable Document Format (PDF) from the NICE
 Web site.
- Etanercept and infliximab for the treatment of psoriatic arthritis. Assessment report. Centre for Reviews and Dissemination/Centre for Health Economics Technology Assessment Group, University of York. 2005 Feb 4. Electronic copies: Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1092. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the <u>original guideline</u> document.

PATIENT RESOURCES

The following is available:

Etanercept and infliximab for the treatment of psoriatic arthritis.
 Understanding NICE guidance. Information for people who use NHS services.
 London (UK): National Institute for Health and Clinical Excellence (NICE);
 2006 Jul. 4 p. (Technology appraisal 104).

Electronic copies: Available in Portable Document Format (PDF) from the <u>National</u> Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1093. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on March 2, 2007. This summary was updated by ECRI Institute on May 15, 2008 following the U.S. Food and Drug Administration advisory on Enbrel (etanercept).

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